

### REMARKS

Claims 1-36 are present in the instant application. No claims have been indicated to be allowable.

#### Claims Objections:

##### 35 USC 103

Claims 1-18 and 19-36 stand rejected under 35 USC 103 (a) as unpatentable over Kodera et al., 6,455,273 B1, Kurtz et al., 5,639,788 and Daravingas et al., 6,235,320 in view of Schwarz et al., 6,149,941 and Mezaache et al., 6,156,512.

##### Office Action Item 5.

Claims 1-18 stand rejected under 35 USC 103 (a) as unpatentable over Kodera et al., 6,455,273 B1, Kurtz et al., 5,639,788 and Daravingas et al., 6,235,320 in view of Schwarz et al., 6,149,941 and Mezaache et al., 6,156,512.

Kodera et al., Kurtz et al., and Daravingas et al., disclose that amino acids, protein hydrolysates, peptides and polypeptides have a bitter taste as stated by Applicant (page 2, second paragraph). The Office Action states that Schwarz et al. disclose the addition of flavor improvers such as sucralose". The Office Action states that Mezaache et al. disclose "dosage forms containing taste masking coatings that contain sweeteners such as sucralose".

On examination of the cited patents, Applicant finds these patents teach away from the use of sucralose as a taste masking agent for bitter tasting substances.

Schwarz et al. states that "attempts to mask especially bitter or chalky active substances have been unsuccessful to date, even by adding flavourings or aromas" col. 1, lines 59-62. One skilled in the art would recognize that previously known flavorings which might be added to improve flavor do not have the ability to overcome bitterness. Sucralose is included in the list of flavorings suggested in col. 2, lines 47-56 as "suitable flavour improvers" and as sweeteners at col. 3, lines 57-61. As such, sucralose must be included in those "unsuccessful" attempts to mask "especially bitter" substances, **thus demonstrating that Schwarz et al teaches that the applicant's present invention would be "unsuccessful" and does not combine with Kodera, Kurtz et al. or Daravingas et al. to show that the present invention would be obvious to one of ordinary skill in the art since these references teach away from the present invention.**

With Schwarz et al. teaching that sucralose was among those flavourings that failed to mask tastes, there would have been no reason to try it at the concentrations of the present invention to mask the bitter tastes of amino acids, proteins, peptides or polypeptides disclosed by Kodera et al., Kurtz et al. and Daravingas et al. and the specific concentrations would not have been obvious.

Mezaache et al., discloses dosage forms "which effectively mask the taste of unpleasant active agent(s) therein" and specifically identifies the taste masking agent as coatings: "Highly useful dosage forms result when microspheres made from compositions containing active agents, solubilizers and spheronization aids are coated with taste-masking agents" Col.2, Line 55-56 and "coating the particles of step (1) with a cellulosic taste-masking material, " col.3, line 17.

Mezaache et al demonstrate that the particles containing the bitter active ingredient are encapsulated for “taste masking” prior to the addition of the sweetener (see Example III, col.13, line 47), in this case acesulfam K. Mezaache et al. were not aware of the taste masking potential of sucralose as they masked the bitterness in their Examples prior to the addition of the sweetener, acesulfame potassium, one of the list containing sucralose at col. 12, lines 16-30.

**Thus, Mezaache et al. teaches away from method of the the instant invention.**

**Schwarz et al. and Mezaache et al. do not contain any justification to support their combination for using a taste masking quantity of sucralose as a taste masking agent for the bitter taste of the amino acids, polypeptides, or proteins or the assumption that one having ordinary skill in the art would have been led to combine the teachings of the cited references to arrive at the claimed invention.**

In the instant invention, Applicant has not merely used sucralose as a sweetener as both Schwarz et al. and Mezaache et al. have done but have found a completely unobvious utility for sucralose at taste masking levels to reduce the bitterness of amino acids, their analogs, proteins, peptides and protein hydrolysates. The clear intention of Koder et al., Kurtz et al., Daravingas et al., Schwarz et al., and Mezaache et al. have been to overcome a significant problem in both the aforementioned nutritionals and each has found a new and improved method of doing so, however, none of the aforementioned Patentees have found Applicant’s unobvious and unique use of sucralose as a taste masking agent in the aforementioned nutritionals and in fact teach away from the instant application.

#### **Office Action Item 6**

Schwarz et al. states that “attempts to mask especially bitter or chalky active substances have been unsuccessful to date, even by adding flavourings or aromas” col. 1, lines 59-62. One skilled in the art would recognize that previously known flavorings which might be added to improve flavor do not have the ability to overcome bitterness. Sucralose is included in the list of flavorings suggested in col. 2, lines 47-56 as “suitable flavour improvers” and as sweeteners at col. 3, lines 57-61. As such, sucralose must be included in those “unsuccessful” attempts to mask “especially bitter” substances, thus demonstrating that Schwarz et al teaches that the applicant’s present invention would be “unsuccessful” and does not combine with Koder et al., Kurtz et al. or Daravingas et al. to show that the present invention would be obvious to one of ordinary skill in the art since these references teach away from the present invention.

With Schwarz et al. teaching that sucralose was among those flavourings that failed to mask tastes, there would have been no reason to try the methods of the present invention to mask the bitter tastes of amino acids, proteins, peptides or polypeptides disclosed by Koder et al., Kurtz et al. and Daravingas et al. and the specific concentrations would not have been obvious.

Mezaache et al., discloses dosage forms “which effectively mask the taste of unpleasant active agent(s) therein” and specifically identifies the taste masking agent as coatings: “Highly useful dosage forms result when microspheres made from compositions containing active agents, solubilizers and spheronization aids are coated with taste-masking agents” Col.2, Line 55-56 and “coating the particles of step (1) with a cellulosic taste-masking material, “ col.3, line 17.

Mezaache ‘152 further narrows the “taste masking” compounds as they state: “It is also preferred that the coating used on the microspheres be one or more cellulosic coatings which

serve to mask the taste of any unpleasant tasting active, or bio-affecting agent(s) in the microspheres. Useful cellulosic coatings include one or more alkylcellulose and/or hydroxyalkylcellulose polymers. Ethyl cellulose(EC)/-hydroxypropylcellulose (HPC) blends are useful, with EC:HPC ratios of 0.1:1 to 2:1 being useful. One preferred combination is a 1:1 blend of these polymers." Col.11, line 33-36.

Thus, one skilled in the art upon carefully reading Mezaache et al would conclude that the "taste masking" technology had nothing to do with sucralose since the particles containing the bitter active ingredient are encapsulated for "taste masking" prior to the addition of the sweetener (Example III, especially col.13, line 47). Mezaache et al. were not aware of the taste masking potential of sucralose as they masked the bitterness in their Examples prior to the addition of the sweetener, acesulfame potassium, one of the list containing sucralose at col. 12, lines 16-30. Thus, Mezaache et al. teaches away from method of the the instant invention.

Schwarz et al. and Mezaache et al. do not contain any justification to support their combination for the method of using sucralose as a taste masking agent for the bitter taste of the amino acids, polypeptides, or proteins or the assumption that one having ordinary skill in the art would have been led to combine the teachings of the cited references to arrive at the claimed invention.

In the instant invention, Applicant has not merely used sucralose as a sweetener as both Schwarz et al. and Mezaache et al. have done but have found a completely unobvious utility for sucralose at taste masking levels to reduce the bitterness of amino acids, their analogs, proteins, peptides and protein hydrolysates. The clear intention of Koder et al., Kurtz et al., Daravingas et al., Schwarz et al., and Mezaache et al. have been to overcome a significant problem in both the aforementioned nutritionals and each has found a new and improved method of doing so, however, none of the aforementioned Patentees have found Applicant's unobvious and unique use of sucralose as a taste masking agent in the aforementioned nutritionals and in fact teach away from the instant application.

**Conclusion**

For all the reasons given above, Applicant respectfully submits that the claimed distinctions are of patentable merit under Section 103. Accordingly, applicant submits that this application is now in full condition for allowance, which action Applicant respectfully solicits.

Respectfully,

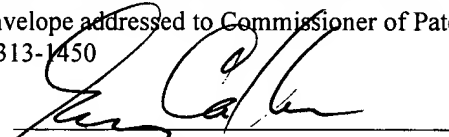


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